4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1659]

Established Conditions: Reportable Chemistry, Manufacturing, and Controls Changes for Approved Drug and Biologic Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products." The purpose of this guidance is to provide applicants of new drug applications, abbreviated new drug applications, and biologic license applications with FDA's current thinking on established conditions (i.e., the chemistry, manufacturing, and controls (CMC) information in a submission that would require reporting to FDA if changed for approved drug and biologic products, per the current regulations). This guidance also describes those sections of a common technical document formatted application that typically contain information that meets the definition of established conditions, and provides considerations for managing changes to established conditions over the life cycle of an approved product.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-2400; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products." The current

regulations for drugs and biologics require applicants with approved drug or biologic products to notify FDA about each change in each condition established in the approved application beyond the variations already provided for in the application (see 21 CFR 314.70) or each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application (see 21 CFR 601.12). FDA guidance documents clarify the recommended reporting mechanism (i.e., supplement, annual report) for postapproval CMC changes. This draft guidance has been developed to address the lack of clarity with respect to what CMC information in an application constitutes an established condition.

A better understanding of which elements of the CMC information constitute established conditions to FDA and where in an application these are generally expected to be described will allow for a more effective postapproval submission strategy (e.g., effective use of risk management principles in the International Conference on Harmonisation (ICH) Q9, and knowledge management as defined in ICH Q10) by the regulated industry. This will also provide the FDA pathways to better regulate postapproval changes by utilizing more flexibility and risk-based principles, as envisioned by the pharmaceutical product quality initiatives laid out in FDA's "Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century--A Risk Based Approach" (see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/UCM071836).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Established Conditions: Reportable CMC Changes for Approved Drug and

Biologic Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 211, 314, and 601 have been approved under OMB control numbers 0910-0139, 0910-0001, and 0910-0338, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-13104 Filed: 5/29/2015 08:45 am; Publication Date: 6/1/2015]